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TITLE: Body Composition in Military or Military Eligible Women

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FOREWORD

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 2/24/98
PI - Signature Date

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IV. INTRODUCTION

All branches of the military have established standards for accession and retention (1-3). The accession standards are based on indirect determinations of body composition from weight for height (W/H) tables, while the retention standards include an assessment of a body composition based on W/H measurements and a test of aerobic fitness. Periodic review of W/H is conducted within all branches of the armed forces. Failure to meet these standards results in anthropometric assessment and determination of percent body fat (% BF) from regression equations based on circumference measurements. However, Vogel et al (4) reported that due to difficulties encountered in predicting body density in African-American females, primarily hydrophobia, the equation selected for use with females was developed from the White population studied. *This means that for technical reasons, the population used to develop the current Army equation did not contain any minority women. This also raises the question of the appropriateness of this equation for broad use within an Army where 53% of the females soldiers are members of minority ethnic groups.*

If the soldier has a higher %BF than allowed, then she undergoes medical review, is assigned to a supervised program of diet and exercise, and is given a set period of time prior to final evaluation. If the soldier does not meet the retention standards, then she is separated from military service. Such a separation results in a loss for both the Armed Forces in terms of training and knowledge lost to the military and for the individual in terms of the loss of a career and benefits. Therefore, it is vital to be certain that the standards selected are fair and unbiased. *If there are age, or ethnic-related biases in the regression equations that estimate %BF, it would be essential that these biases be scientifically quantified, in order to account for them in all retention evaluation procedures.*

The experiment outlined below proposes: to determine the accuracy and precision of the Army and Navy equations to predict percent body fat in minority and non-minority female soldiers across representative ranges of age and body fat; to develop new prediction models using a modern, nonparametric tree-structured model that will be applicable to minority and non-minority female soldiers across all ages and ranges of body fat; and to test the validity of the new prediction models using cross-validation, a computationally-intensive technique.

The recommendation to conduct research into the area of health promotion and disease prevention among military women, is included among those published by the Institute of Medicine in 1995 (6). If the current W/H, body fat and fitness standards of the military were met, then female soldiers would be free of diseases related to overweight and obesity. *In order to ensure a healthy female component of the military it is vital that all female soldiers meet the fitness and body composition standards and that these standards be uniformly applicable across all ethnic groups, ages and ranges of body fatness.*

The results of the proposed experiment will provide the Armed Forces with a scientifically based litmus test of the equations currently being used to estimate %BF, to determine promotion rate and/or retention in the armed forces, and to ensure the health promotion and disease prevention of all minority and non-minority females soldiers.

V. BODY OF PROPOSAL

A. BACKGROUND

Retention standards for all branches of the military include an assessment of a body composition based on weight for height measurements (W/H) and a test of aerobic fitness (1-3). Periodic review of W/H is conducted and failure to meet these standards results in an anthropometric assessment of %BF. If the soldier has a higher %BF than allowed, then she undergoes medical review, is assigned to a program of diet and exercise, and is given a set period of time prior to final evaluation. Separation from the armed service results, if the retention standards are not met.

The current equations to predict %BF, based on circumference measurements, were generated on populations of the services that reflected the proportion of ethnicity of the services in the late 1980's. For example, the Army validation experiment was performed in a population partitioned in the following manner: 21% of the population studied were female and of the females 38% were African-American (AA). In 1995 (5) 53 % of all female soldiers are minority group members and 44% of all female soldiers are AA. These figures illustrate the growing contribution of minority women to the Army.

At that time the only criterion method used was hydrostatic weighing which, because of differences between ethnic groups in bone density, is known to have limited use in a minority populations. Vogel et al (4) reported that due to the higher prevalence of hydrophobia among AA soldiers than among the white soldiers it was difficult to predict body density in AA female soldiers. Therefore, the equation selected for use with females was developed from the population of white female soldiers studied. *This means that for technical reasons, the population used to develop the current Army equation did not contain any minority women.*

Since then, dual energy x-ray absorptiometry (DXA) has become widely available, which overcomes some of the theoretical and practical problems of underwater weighing, in that it quantitates bone density and bone mineral content. In combination with the measurement of body volume from hydrostatic weighing and total body water measurement by isotope dilution, DXA can be used in a four compartment model of body composition validated by Heymsfield et al. (6). *This four compartment model has replaced hydrostatic weighing as the criterion method for determining body composition and accommodates differences between minority groups in bone density and appendicular muscle density.*

Since 44% of the female soldiers in the Army are African-American, the literature on differences between AA and whites is briefly reviewed. Differences in components of body composition between African-Americans and whites have been known for almost four decades (7). The best documented difference in body composition between these two ethnic groups is an increased density of the fat free mass (FFM) in African-Americans because of a heavier and denser skeletal mass, and denser appendicular muscle mass (8-11). In 1990, Zillikens and Conway (12) suggested a difference in location of adipose tissue stores, specifically that African-American women have greater upper body obesity as compared to white women based on skinfold thickness ratios. A larger subscapula skinfold has been reported in a large population of African-American women, who are described in the CARDIA study (13). Apparently this centrality of fat deposition patterns begins in childhood, since AA have a more central pattern of fat deposition than white children (14). The fat distribution differences between AA and white children are evident in the preschool period and through adolescence into adulthood. Mueller (14) further reported that the ethnic trends of fat

deposition patterns were independent of fatness level, socioeconomic status, and age, suggesting a possible genetic component to fat deposition patterns. *Because of these differences in fat deposition patterns, an ethnically based regression equation or a regression model that can account for ethnic differences is needed.*

A major objective of the present study is to evaluate the existing Army and Navy models for predicting body fat and to develop new models for predicting body fat and lean body mass that adequately accommodate minority and non-minority military women across all ranges of age and body fat.

B. HYPOTHESES

1. The Army and Navy regression equations for estimation of percent body fat apply to minority and non-minority military or military-eligible females across all applicable ranges of age and body fat with less than 5 soldiers out of 100 misclassified for retention.
2. The agreement between the Army and Navy regression equations and the four compartment model criterion method will show an acceptable concordance correlation.
3. The new prediction equations for estimation of percent body fat apply to minority and non-minority military or military-eligible females across all applicable ranges of age and body fat with less than 5 soldiers out of 100 misclassified for retention.
4. The accuracy and precision of the new equations for predicting the body fat or lean body mass developed from the four compartment criterion method will be acceptable based on the concordance correlation coefficient.

C. TECHNICAL OBJECTIVES

1. To determine the accuracy and precision of the Army and Navy equations to predict percent body fat in minority and non-minority female soldiers across all ages and ranges of body fat.
2. To develop new prediction models using a modern, nonparametric tree-structured model that will be applicable to minority and non-minority female soldiers across all ages and ranges of body fat.
3. To test the validity of the new prediction models using cross-validation, a modern computationally-intensive technique.

D. SUBJECT SELECTION

This study will include a total of 250 normal weight women, selected according to the following

admission criteria:

- Age range 17-40
- Body weight based on Army retention criteria
- Broadly representative of the ethnic composition of the Armed Forces, which in 1995 was: 40% minority (31% African-American, 5% Hispanic, 2.5% Asian-American/Pacific Islander, and 1.5% Native American) and 60% non-minority.
- Broadly representative of the age distribution of the Armed Forces, which in 1995 was:
≤ 20 y, 15.6%; 21-25 y, 31.6%; 26-30y, 20.3%; 36-40y, 10.8%; 41-45 y, 4.4%; >45y, 1.3%.
- Members of the military and/or military-eligible
- Absence of hydrophobia
- Free of major metabolic disease such as: diabetes and cardiovascular disease

Recruitment and medical screening will be conducted by a research assistant under the close supervision of the principal investigator. Participants will be recruited from members of the armed services in the metropolitan San Diego, CA area, by means of ads placed in local editions of the armed forces newspapers and in the San Diego newspaper.

E. SAMPLE SIZE

Since the goal of this experiment is to test and develop prediction equations and not to test a true null hypothesis, standard power analysis does not apply. Therefore sample size was determined based on the standard requirement of having at least 10 subjects per predictor variable to develop a multiple regression equation. We have approximately 25 predictor variables (see planned analysis section). Consequently, we have chosen a sample size of 250 military or military-eligible women with an approximate population distribution 149 whites and 101 from other ethnic groups. In addition, Lohman (15) demonstrated that it is necessary to have at least 50 subjects per experiment to develop validation equations. The proposed sample size of 250 will include ~75 AA women and a total of 100 ethnic minorities, which would be sufficient to develop a separate ethnically based equation or model if needed.

F. BODY COMPOSITION MEASUREMENTS

1. Anthropometry

The anthropometric measurements will include skinfolds at the triceps, biceps, subscapula, and suprailiac and circumferences at the following sites: neck, upper arm, forearm, wrist, chest, abdomen (midway between the lowest rib and the iliac crest, 16), hip, thigh, and calf. These measurements will be made according to Lohman et al., (17). All available military service equations (4, 18, 19) will be tested.

2. Fat Patterning

The ratio of the triceps to subscapula skinfold thickness has been demonstrated to vary in ethnic groups (12), and Mueller (14) has reported that the subscapula skinfold thickness may be indicative of genetic differences in fat patterning. Other indices of fat patterning will also be determined, i.e., waist to hip ratio (WHR) which is the ratio between the abdominal circumference divided by hip circumference, and sagittal diameter (SagD) using the Holtain abdominal caliper at the site of the fourth lumbar (20). Both of these have been reported to be anthropometric surrogates for visceral adipose tissue in minority and non-minority women (20-23). All of these anthropometric indices of fat patterning will be included as a predictor variable offered to the CART procedure.

3. Isotope Dilution

Each subject will report to the Human Study Facility by 7:00 A.M. after a twelve hour overnight fast. Weight will be determined to ± 0.001 kg, height will be determined to ± 0.01 cm. by means of an Holtain stadiometer. A 20g dose of 99.975% deuterium oxide ($^2\text{H}_2\text{O}$) administered upon arrival in the lab and after the collection of a respiratory water sample. Additional samples will be collected at approximately 3 and 4 hours afterwards. The samples will be analyzed using a Miran (The Foxboro Co., Norwalk, Conn.) infrared spectrophotometer. Percent body fat from D_2O will be calculated using standard isotope dilution equations. Total body water will be determined in liters. Correction will be made for non-aqueous exchange of hydrogen, isotopic fractionation. All values will be converted to kilograms using the constant 0.009934. This method has a day to day CV of $<2.5\%$.

4. Hydrodensitometry

Body density will be measured by using a hydrodensitometry system described previously (24). After complete submersion and maximal expiration by the subject underwater weight will be recorded by four platform force transducers. The subjects will be asked to perform three training trials and then three additional trials. The underwater weight will be recorded as a average of the last three trials. Density will be corrected for residual lung volume which will be measured simultaneously with underwater weight by means of a closed system nitrogen dilution system.

5. Dual Energy X-ray Absorptiometry

The dual energy x-ray absorptiometer (DXA) consists of a scan table, a computer monitor, a keyboard, and a printer. The scan table contains the x-ray generator, detector, and system electronics used to process the signals from the detected x-rays. One scan gives measurements of % BF, fat and lean tissue mass, and bone density and bone mineral content. Each scan takes approximately 20-30 minutes depending on the body composition of the individual. The radiation dose of 0.024-0.06 mRem is 1/800-1/1000 of the radiation received from a single chest x-ray exposure (40 mRem) or to whole body dose incurred each year due to cosmic radiation and natural radiation sources such as radon, thorium and potassium.

Measurements will be done using the Lunar DXA scanner. The subjects will be asked to change into a hospital gown and remove any metal objects to avoid possible attenuation of x-ray beam from watches, zippers, buckles and buttons. Any subjects with surgically placed metal implants or shrapnel will be excluded. In addition, the machine can only scan individuals between 25-196 cm long and 36-113 kg in weight. The subject lies in the supine position on the scanning table. Measurements will be taken at the speed appropriate for their body composition and will take 15 to 30 minutes and the subject receives up to 0.06 mrems of radiation. All measurements will be done by the same technician to avoid variability.

G. Four-Compartment Model

This model is an extension of one of Siri's models (25):

Body Weight = Aqueous weight + Mineral weight + Protein weight + Fat weight
and

Fat Free Mass = Aqueous weight + Protein weight + Mineral weight

where aqueous weight can be determined by isotope dilution, mineral weight from DXA, body density and body volume from hydrodensitometry; fat mass or fat free mass can then be obtained

using the algebraic equations given by Heymsfield et al., (6).

H. PRELIMINARY DATA

To date no data have been collected due to re-assignment of the original PI and transfer of the project to Dr. Marta Van Loan at the US Department of Agriculture's Western Human Nutrition Research Center (WHNRC) in San Francisco, CA. and co-PI Dr. James Hodgdon at the Naval Health Research Center (NHRC) in San Diego, CA.

I. STATISTICAL METHODS

1. Data Analysis

The data will be entered and independently verified by assistants. Data will be analyzed using the multiple regression analysis and where appropriate the CART module of the SYSTAT package. These analyses will be done in conjunction and consultation with the statisticians at WHNRC and NHRC.

We will fit two regression trees and three classification trees. The two continuous response variables for the regression trees will be:

1. Percentage body fat from a four compartment model (6) and
2. Lean body mass.

The three categorical response variables for the classification trees are:

1. Binary variable for the *DoD-wide goal* for female soldiers of $\leq 26\%$ body fat (Army Regulation 600-9). The two levels are ≤ 26 and $>26\%$ body fat.
2. Five-level categorical variable for the *retention cutoffs* for each age groups: for 17-20y $\leq 28\%$ BF, for 21-27y between 28 and 30% BF, for 28-39y between 28 and 30% BF, and for 40 & older $> 34\%$ BF.
3. Six-level categorical variable including the *DoD goal* and the *retention cutoffs*: $\leq 26\%$ body fat, for 17-20y between 26 and 28% BF, for 21-27y between 28 and 30% BF, for 28-39y between 28 and 30% BF, and for 40 & older $> 34\%$ BF.

All the regression and classification trees will use approximately 25 predictor variables:

- skinfold thicknesses measurements such as: triceps, biceps, subscapula, and suprailiac
- circumference measurements such as: neck, chest, upper arm, forearm, wrist, abdominal, hip, thigh, calf, including standard functions of them such as waist to hip ratio (WHR)
- Other anthropometric variables such as height and weight, including standard functions of them such as weight/height² or body mass index (BMI)
- Sagittal Diameter as measured by Holtain abdominal caliper
- Age
- Ethnic group
- Menstrual status
- Parity
- General health status

Statistical methods will also be used to evaluate the agreement between the actual percentage fat and that predicted by the Army and Navy regression models:

- For the comparison of two methods, Bland and Altman (26-27) recommend plotting the difference versus the mean. These *Bland-Altman plots* describe agreement better than conventional methods such as the Pearson correlation coefficient and linear regression.
- Lin (28) introduced the *concordance correlation coefficient* to quantify the agreement between two methods. The concordance correlation is the product of the Pearson correlation (measure of precision) and a bias correction factor (measure of accuracy). Lin (29) discusses statistical methods for evaluating the acceptability of the concordance correlation coefficient.
- The *misclassification error rate* corresponding to the various standard cutoffs for ascension and retention will be used to evaluate the practical effect of using the existing prediction equations. Misclassification error can be adjusted to allow for unequal costs of erroneously rejecting subjects and incorrectly accepting subjects.

Regression models will be developed to predict percentage fat and fat free mass from the anthropometric measurements. In addition, classification models will be developed to predict whether individuals fall in classes defined by the standard cutoffs for percentage fat. The conventional statistical methods for constructing these prediction models are multiple linear regression and discriminant analysis.

VI. CONCLUSIONS:

None

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VIII. APPENDICES:

Attached Human Subjects Protocol. This protocol is a revision of an existing, approved protocol on the Estimation of Body Composition of US Marine Corps and Other Military Personnel. Imbedded within this revised protocol are the military minority women. Use of this protocol will ensure that approval is granted in a timely matter and that the project will finish with a two year period.

HUMAN USE PROTOCOL ROUTING SLIP

FROM:
Kathleen I. Kujawa

In accordance with NMRDCINST 3900.2 of 07 June 1993, I am submitting the attached Human Use Protocol for consideration.

TITLE OF PROTOCOL: Estimation of Body Composition of U.S. Marine Corps and Other Military Personnel.

PROPOSED DATES OF RESEARCH: 971201 to 990930

SUBMISSION (CHECK ONE):

☐ INITIAL SUBMISSION
☒ MODIFICATION OF PREVIOUS SUBMISSION
☐ CONTINUING/ANNUAL REVIEW

PROTOCOL OBJECTIVE (Brief sentence or two):

The objectives of this study are to (a) validate the current circumference equations used by the U.S. Marine Corps to estimate percent body fat and (b) conduct a field survey of body composition of U.S. Marine Corps personnel, (c) validate the use of whole-body electrical impedance spectroscopy to measure total body water, and (d) to investigate affects of ethnic group membership on prediction of body composition in women.

COMMENTS (e.g., issues, special considerations):

The scope of work under this protocol is being increased to meet the objectives of a Department of Agriculture contract. The title is modified to indicate this increase in scope. The number of subjects studied is being increased, the description of subjects is being changed, the site for carrying out the study is being changed (from NTC to FCTCPAC), and the dates encompassed by the protocol are being extended. Within the body of the protocol, changes are indicated by bold type.

DoD PROTOCOL NUMBER: 31251

		DATE RECEIVED	DATE APPROVED	INITIALS
1	DIVISION HEAD			
2	DEPARTMENT HEAD			
3	DEPARTMENT CPHS MEMBER			
4	SCIENTIFIC DIRECTOR			
5	CPHS RECORDER			
6	COMMANDING OFFICER			

I. COVER PAGE(S)

1. Protocol Number: 31251
2. Title: Estimation of Body Composition of U.S. Marine Corps and Other Military Personnel.
3. Date of Submission: Nov 1997
4. Approved Work Unit: Studies of Body Composition in U.S. Navy Personnel; BUPERS Reimb. PS006-6430
5. Approximate Dates of Research: 971201 to 990930
6. Principal Investigator: LCDR Kathleen I. Kujawa, MSC, USN
7. Co-Investigator(s): M. Katherine Canine, M.A.
James A. Hodgdon, Ph.D.
8. Primary Performing Institution(s): NAVHLTHRSCHCEN
9. Collaborating Institution(s): N/A
10.
 - a. Number of Subjects: 2200
 - b. Number of Female Subjects: 800
 - c. Number of Male Subjects: 1400
 - d. Number of Civilian Subjects: 0
 - e. Number of Active-Duty Subjects: 2200
11. Identification of Medical Monitor: Gray, Gregory C., CAPT, MC, USN
12. CRDA Initiated? (Y/N): N

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III. RECORD OF CHANGES TO THE PROTOCOL

12 Feb. 1998: The scope of the laboratory study (but not the field study) was increased to include meeting the objectives of a Dept. of Agriculture, Defense Women's Health Research Program, project entitled "Body Composition in Military or Military Eligible Women". The method for measurement of total body water by deuterium oxide dilution was modified from urinary to respiratory water collection and analysis to maintain consistency with the DWHRP procedures. Three hundred subjects were added to the protocol: 20 women in each of 5 age groups, for each of 3 ethnic groups (Hispanics, Asian-Americans, and Pacific Islanders), to achieve the sample ethnic diversity called for in the DWHRP proposal. The dates of the protocol were extended to 30 Sep 1999 to reflect an increase in time needed to recruit and measure the additional subjects.

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V. SCIENTIFIC BACKGROUND AND OBJECTIVES

1. Background

U.S. Marine Corps (USMC) personnel who exceed the USMC body weight standards for a given height must have their percent body fat measured using the USMC circumference equations. For men, the circumferences measured are the neck and abdomen; for women, the circumferences measured are the neck, abdomen, biceps, forearm, and thigh. The equations used are unique to USMC (MCO 6100.10B). The Commandant of the Marine Corps has recently tasked the Training Programs Branch, Training and Education Division (MCCDC) with validating the equations used by USMC for male and female Marines of different age groups. In conjunction, the Commandant also requested a survey of body composition of USMC personnel to assist in validating or realigning weight-for-height standards. Training Programs Branch, Training and Education Division, MCCDC, has requested that Naval Health Research Center's Human Performance Department conduct this work.

The U.S. Army, under the Defense Women's Health Research Program (DWHRP), contracted with the U.S. Department of Agriculture to carry out a study of prediction of body composition in military females, with special reference to ethnicity as a moderator of percent fat prediction from anthropometry. The study is to use a four-compartment determination of body composition as the criterion measure. The Department of Agriculture is entering into an agreement with NHRC to carry out this DWHRP project. In that NHRC has already conducted a similar study investigating ethnic differences between whites and blacks, extant data can be used to address some of the aims of the DWHRP program. What remains to be done is to validate the use of Whole-body Impedance Spectroscopy as a predictor of total body water, and to increase the range of ethnic groups over that of our previous study. Since the techniques, and measurements to be used were identical to those requested by the U.S. Marine Corps, it was deemed best to expand the scope of the current Marine Corps study rather than develop a new protocol which was almost identical to an existing one.

2. Objectives

a. Hypothesis(es) to be tested

NA

b. Other objective(s)

The objectives of this study are (a) to validate the circumference equations used by USMC to predict percent body fat in males and females. Validation will be determined by age groups; (b) to conduct a field survey of body composition of USMC personnel, using a sample representative of the age and gender demographics of the Corps. © to validate the use of whole-body impedance spectroscopy as a measure of total body water. (d) to determine whether or not ethnicity affects

the prediction of percent body fat of women from anthropometric measures.

VI. EXPERIMENTAL METHODS

1. Experimental Procedures and Rationale

a. Subjects

Subjects (n = 200; 100 male, 100 female) for the Marine Corps validation portion of the study will be recruited from among USMC active-duty personnel in the San Diego County region. Subjects (n = 1700; 1300 male, 400 female) for the field survey will be recruited from among USMC active-duty personnel in the San Diego County region and at Camp Lejeune, NC. If necessary to ensure a demographically balanced sample, recruitment will also take place in the Washington, DC, area. To meet the DWHRP project needs, an additional set of 300 subjects: all female, 100 Hispanics, 100 Pacific Islanders, and 100 Asians will be recruited for the laboratory study from among active-duty military personnel in the greater southern California area. Data on black and white personnel will be drawn from archival data.

b. Methods

Validation Study

Body composition will be determined by the four-compartment method (Friedl, DeLuca, Marchitelli & Vogel, 1992). Percent body fat as determined by the four-compartment method will then be used as the criterion against which the USMC circumference equations are validated. Body composition assessment will take approximately 4.5 hr and will occur at the Human Performance Laboratory located in Building 74, Fleet Combat Training Center, Pacific (FCTCPAC), San Diego. The subjects will undergo five different types of tests and will complete a Current Physical Activity Questionnaire (see Appendix G).

Each subject will be measured once. The following tests will be performed:

1. Anthropometry - Body weight, height, 10 skinfolds, 10 bone breadths, and 18 body circumferences will be measured to determine body configuration. These data will be used to determine percent body fat by the USMC circumference equations. The additional anthropometric measurements will be used to determine if there is a more accurate method for determining percent body fat using alternate predictor variables that USMC could adopt.

2. Dual-energy x-ray absorptiometry (DEXA) - DEXA will be used to determine bone mineral content, bone density, and bone mass. Subjects will lie supine on a padded table for 12 min while a low-energy x-ray beam scans the entire body. The radiation dose is very low, 1 mrem, which is equivalent to one 250th of normal

annual background radiation, one 9th of the radiation received in a transatlantic flight, or one 30th of a chest x-ray. These measurements will be used in the four-compartment body composition estimation equation (Friedl, DeLuca, Marchitelli & Vogel, 1992).

3. Bioimpedance analysis (BIA)- A bioimpedance analyzer (Xitron, San Diego, CA) will be used to determine total body water, a component in the four-compartment model. An imperceptible current (250 uA at 5 KHz to 500 KHz) will be passed through the body. The resistance to the current (impedance) will be measured. Due to the electrolytes in body water, tissue impedance is directly related to body water content. Patel, Matthie, Withers, Peterson, and Zarowitz (1994) and Van Loan, Withers, Matthie, and Mayclin (1993) have shown that BIA accounted for 99% of the variance in total body water as determined by the criterion method of deuterium dilution.

4. Deuterium oxide dilution - Subjects will ingest 25 g of deuterium oxide (D2O), a naturally occurring form of water with a stable isotope of hydrogen, to validate total body water values obtained with the Xitron bioimpedance analyzer used in this study. Prior to ingestion, 3 hours post ingestion, and 4 hours post ingestion of the D2O, respiratory water will be collected. Respiratory water will be obtained by having the subjects inhale nasally and exhale orally through a 1.5 meter length of tubing. After the subjects' breath passes through the tubing, concentric loops of the tubing will be submerged in an methanol-dry ice bath at 60°C. Submerging the tubing will cause respiratory vapors to condense on the inside of the tubing. The subject will continue to breath, inhaling nasally and exhaling orally, through the tubing for 6 to 15 min. After the collection period, the condensed respiratory vapors will be thawed and poured into a microtube for storage. Samples will be coded to protect subject identity and shipped to the U.S. Department of Agriculture Western Human Nutrition Research Center, San Francisco, CA, for analysis. On 20 of the subjects, a urine sample will be obtained from the subject two to three hours after ingestion. An aliquot of urine will be frozen for shipment and analysis by mass spectrophotometry at the Pennington Biomedical Research Center, Baton Rouge, LA. Samples will be coded prior to shipment to protect subject identity. Results of the analysis will be used as a quality assurance check on the respiratory water determination of total body water.

5. Hydrostatic (underwater) weighing and residual lung volume - Underwater weighing will be conducted in a rectangular (7 feet long x 4 feet wide x 5 feet deep), glass-fronted tank of heated water (35°C/96°F). The swimsuit-clad subject will sit on a chair suspended from a load cell that generates an electrical signal in proportion to the weight of the subject. The weight of the chair is zeroed out. Signals from the load cell will be fed into a computer. The subject will be asked to exhale completely while bending forward at the waist to submerge the entire body. This procedure will be repeated (after a rest interval) until 6 to 10

underwater weights are obtained. Residual lung volume will be determined by the helium dilution method (Ruppel, 1975). The subject will wear a nose clip and breathe through a mouthpiece and hose connected to a closed-circuit spirometer containing ambient air and helium (5% to 10%). After exhaling maximally, the subject will breathe quietly on the system for 4 min to 5 min (approximately 250 cc/min oxygen supplied continuously), and then exhale maximally again. The residual volume will be calculated from the change in helium concentration before and after the subject breathes on the system. Body volume will be determined from the underwater weighing data and residual lung volume. Body density (mass/volume) will be estimated from the body weight measured in air and the body volume.

Field Survey of Body Composition

A field survey of body composition of USMC personnel will be conducted. The sample will reflect USMC age and gender demographics. Percent body fat of active-duty USMC personnel will be determined using the USMC circumference equations. Skinfolts also will be taken to serve as a cross-check on the circumference equations. The following measurements will be made:

Height, weight, circumferences (5 sites), skinfolts (10 sites).

This study will not involve animal use; investigational drugs, devices, or biologics; recombinant DNA research, retrovirology; or unusual personnel or environmental hazards.

2. Sample Size Determination.

Validation Study

The validation sample sizes were fixed on the basis of resource availability. For validation of USMC equations against the four-compartment body composition model, equal numbers of men and women will be tested. The number of subjects was set at 100 for each gender. Within genders, the subjects will be divided equally into five age groups. The five age groups were selected from the age distribution quintiles of active-duty USMC personnel in FY96 (the most recent year for which data are available) and are Group I: 17 to 19 years of age, Group II: 20 to 21 years of age, Group III: 22 to 24 years of age, Group IV: 25 to 30 years of age, and Group V: 31+ years of age.

Fixed sample sizes shift the focus of power analysis. Instead of hypothesizing a specific effect size then computing the required sample size, the present analysis states the sample size, then computes the detectable effect size. Detectable effect size is defined as:

$$z_e \geq z_\alpha + z_\beta \quad (\text{Equation 1})$$

where z_e is the detectable effect size expressed as a standardized variable, z_α is the standardized score for the chosen Type I error

level, and z_β is the standardized score for the chosen Type II error level (i.e., power).

The significance and power criteria determine the size of z_α and z_β . Directional hypotheses will be tested, so a one-tailed probability is appropriate for setting Type I error. With $\alpha < .05$ as the significance criterion and $\beta = .80$ as the power criterion, Equation 1 becomes:

$$z_e = (z_\alpha + z_\beta) = 1.65 + 0.81 = 2.46$$

The remainder of this analysis describes the procedures for estimating the effects size associated with z_e . Any effect that is as large or larger than z_e will be detectable with a power of $\beta = .80$ given the proposed sample sizes.

The four-compartment model is expected to provide more accurate estimation of true body composition values than do circumference-based equations. Improved accuracy equals higher criterion reliability, thereby implying stronger relationships to other variables (Nunnally and Bernstein, 1994). This expectation leads to the following null and alternative hypotheses:

$$\begin{aligned} H_0 : r_2 &\geq r_4 \\ H_1 : r_2 &< r_4 \end{aligned}$$

where r_2 is the correlation between Siri (two-compartment) fat (derived from underwater weighing) and the estimated percent body fat computed from circumferences, and r_4 is the corresponding correlation for the four-compartment model.

The minimum detectable effect was computed by solving the following equation:

$$(z_{F4} - z_{F2}) * \sqrt{(N - 3)} = 2.46$$

$$(z_{F4} - z_{F2}) = (2.46 / \sqrt{(N - 3)})$$

$$z_{F4} = (2.46 / \sqrt{(N - 3)}) + z_{F2} \quad (\text{Equation 2})$$

In the preceding equations, z_{F2} and z_{F4} refer to the Fisher r-to-z transformations of the correlations r_2 and r_4 in the null and alternative hypotheses. The difference between z_{F4} and z_{F2} is the effect of interest. Once the equations are solved for z_{F4} , the Fisher r-to-z transformation must be reversed to obtain the actual correlation coefficient of interest.

The last equation provides an estimate of z_{F4} if z_{F2} and N are known. As previously indicated, $N = 100$ for this study. z_{F2} estimates were taken from prior research in U.S. Navy personnel. In that population, the two-compartment estimates of percent body fat correlated $r = .79$ with Sirifat for females and $r = .85$ for males. Inserting these correlations and $N = 100$ into Equation 2, the minimum correlations required to produce a detectable difference ($p < .05$, power = .80) was $r = .867$ for females and $r = .906$ for males.

DWHRP Project

To meet the DWHRP Project needs, females in three ethnic groups need to be sampled: Asian Americans, Pacific Islanders and Hispanics. Extending the design for the Marine Corps validation study, we will have 20 subjects per cell, for each of the 5 age groups previously described, giving a total of 300 subjects.

Field Study

For the field study of body composition of active-duty Marines, 1700 Marines (1300 male, 400 female) will be measured. The 1700 represents approximately 0.8% of active-duty males, while the 400 represents approximately 5% of active-duty females. Females will be oversampled due to their very small total numbers in the active force (8,564 vs. 166,319 males, FY96). USMC is interested in body composition by age groups, so subjects will again be evenly divided into age groups as previously detailed.

3. Justification for Exclusion of Specific Groups

Pregnant women will be excluded from this study. Pregnancy causes short-term changes in body composition that make pregnant women unsuitable for inclusion in a study of body composition of the Marine Corps. In addition, although the small amount of radiation exposure experienced during a DEXA whole body scan poses negligible risk to a fetus, it is still advisable for pregnant women to avoid unnecessary radiation exposure.

Active-duty personnel from services other than USMC will be excluded from the Marine Corps validation and field studies. This is at the request of USMC and reflects its desire to validate its body fat prediction equation against the population in which it is used (i.e., active-duty Marines). The field survey of body composition of active-duty Marines is designed to determine, by age group and gender, the percent body fat of the average Marine.

Males and white and black females will be excluded from the DWHRP study. The specific goals of the project address the influence of ethnicity on the prediction of body composition in women only. White and black women are excluded because archival data exist to meet the study goals, and there is no need to expose additional subjects to the study risks.

4. Required Equipment and Supplies (as needed to ensure proper coordination of research effort)

The following equipment, materials, and supplies will be used in this study:

- a. Major Equipment Items
 1. DEXA (QDR-1500 bone densitometer)

2. Bioelectrical Impedance Analyzer (Xitron 4000B)
 3. Collins Modular Lung Analyzer
 4. Hydrostatic Weighing Tank
- b. Minor Equipment Items
1. Height and Weight Scales
 2. Skinfold Calipers
 3. Measuring Tape
 4. Sliding Caliper
- c. Supplies
1. Data Sheets
 2. Data Diskettes
 3. Printer Paper
 4. Impedance Electrodes
 5. Drierite
 6. Sodasorb
 7. Water Treatment Chemicals (chlorine and soda ash)
 8. Chemical Test Kit (for water in hydrostatic tank)
 9. Propane (for hydrostatic tank water heater)
 10. Nose Clips
 11. Cotton Gauze (2 X 2 and 4 X 4)
 12. Deuterium Oxide
 13. Urine Cups
 14. Shipping Containers
 15. Methanol
 16. Dry Ice
 17. Tygon® tubing
 18. Erlenmeyer flasks

VII. ORGANIZATION OF RESEARCH EFFORT

1. Duties and Responsibilities

LCDR Kathleen Kujawa will serve as Principal Investigator and will provide overall direction for the study and will be responsible for carrying out data analysis. Ms. Katherine Canine shall assume responsibility for all test protocols, procedures, data collection, and will also carry out data analysis. Ms. Canine and LCDR Kujawa may receive assistance in all aspects of testing, data collection, and data analysis from student research assistants. Dr. James Hodgdon will provide technical expertise and supervision for data analysis and report generation.

2. Chain of Command

On a day-to-day basis, LCDR Kujawa and Ms. Canine will be responsible for conduct of the protocol. The research assistants will be responsible for carrying out specific parts of the protocol, including data collection and data analysis. In the chain of command, the student research assistants will report to Ms. Canine, and Ms. Canine will report to LCDR Kujawa.

In the case of medical untoward events, LCDR Kujawa, Ms. Canine, and student research assistants will report to the naval corpsman. The corpsman will answer to the NHRC medical monitor, Dr. Greg Gray, and/or medical officers from the NTC medical clinic.

VIII. RISKS AND DISCOMFORTS TO RESEARCH VOLUNTEERS

1. Risk to the Volunteer and Means of Mitigation

Risks. All of the experimental procedures used in this study pose little or no risk to the subject.

No risk is associated with anthropometry, D₂O dilution, or bioimpedance analysis. The pinching of skinfolds via calipers may cause slight discomfort.

Little risk is posed by the radiation dose of the 12-min, whole body DEXA scan (1.0 mrem). This dose is equivalent to approximately one 250th of normal annual background radiation, one 9th of the radiation received in a transatlantic flight, or one 30th of the radiation received in a chest x-ray.

Residual lung volume measurement can cause slight discomfort associated with breathing through a mouthpiece and wearing a nose clip. If the subject experiences distress while breathing into the spirometer, he or she need only remove the mouthpiece to discontinue the test.

There is a slight risk of inhaling water during underwater weighing. This event is unlikely, and if it occurs, the risk to life is minimal since sitting up will bring the head above the water surface. A theoretical risk of drowning exists, although none has ever been reported during the 30 years of widespread use of this technique. Subjects may experience apprehension at being told to submerge themselves or at becoming submerged. Subjects act as their own monitors, however, and if the anxiety is too great, they may remove themselves from the study. All testing staff are trained in CPR and procedures for quickly extricating an unconscious person from the underwater weighing tank.

The corpsman will review health records and/or medical history questionnaires and approve participation of each subject. Subjects with any preexisting condition that makes them unsuitable for this protocol will not be accepted into the study. Conditions that might skew test results, and therefore lead to exclusion, include bone implants; surgical staples; pacemakers; radioactive seeds; foreign bodies; a history of lead, mercury, or heavy metal poisoning; treatment with colloidal gold; ostomy devices; a history of aortic calcification or kidney stones; treatment within the past 2 weeks with contrast materials (e.g., barium, iodine, radio-opaque catheters and tubes, or isotopes); and pregnancy. During the testing, the medical monitor, Dr. Greg Gray, will not be on site, but he can be reached by phone should any problem arise. In addition, the emergency medical clinic at NTC is staffed and can respond quickly in an emergency.

2. Special Risks to Pregnant Women

The National Council on Radiation Protection and Measurements (NCRP) states in its report #54, "Medical Exposure of Pregnant and Potentially Pregnant Women" (24):

"The risk (to the embryo/fetus) is considered to be negligible at 5 rad or less when compared with the other risks of pregnancy, and the risk of malformations is significantly increased above control levels only at doses above 15 rad."

The radiation dose of the DEXA whole body scan is 1 mrem, which is equivalent to 1 mrad or one 5000th of the 5 rad NCRP limit previously stated. The DEXA scan, therefore, can be considered to pose a negligible risk to a fetus. However, all prospective female subjects will be specifically informed about the risk posed by radiation during pregnancy and will be queried about the possibility of pregnancy both in writing prior to acceptance into the study, and verbally immediately prior to the administration of the DEXA scan. Women who are pregnant or think they might be pregnant will not be allowed to participate.

3. Safety Precautions and Emergency Procedures

All testing staff are CPR certified and will be thoroughly trained in test administration. Subjects will be monitored continuously. Each subject's medical history questionnaire will be screened prior to acceptance into the study. Staff are trained in extrication of an unconscious person from the hydrostatic weighing tank. Phones are available in the laboratory to summon an ambulance in the event of an emergency. The DEXA whole body scan radiation dose reported in this protocol (1 mrem) has been verified by the Radiation Safety Office, Naval Medical Center, San Diego, CA. The Radiation Safety Office also has surveyed and approved the DEXA system as it is set up in our laboratory.

4. Assessment of Sufficiency of Plans to Deal With Untoward Events or Injuries

Previous studies at NHRC involving similar procedures have never led to significant injury of a subject. The use of standard Navy medical procedures has been deemed sufficient to deal with any untoward events and/or injuries. In 1995, when the emergency medical system (EMS) was called for an instance of syncope in a subject walking on a motorized treadmill while carrying a pack, the response time was less than 5 min, which should be adequate to deal with any emergency conditions that may arise.

5. Qualification of Medical Monitor and Medical Support Personnel

CAPT Gregory C. Gray graduated from the U.S. Naval Academy in 1977. He received his M.D. from the University of Alabama in 1983, received his M.P.H. from Johns Hopkins University in 1987, and

completed a residency in general preventive medicine at Walter Reed Army Institute of Research in 1988. He has specialty boards in public health and general preventive medicine (1989). Formerly head of epidemiology departments at two other Navy commands, he currently serves as principal investigator at NHRC for large, DoD epidemiological studies.

IX. DESCRIPTION OF THE SYSTEM FOR MAINTENANCE OF RECORDS

1. Experimental Data

In conjunction with this study, experimental data will be gathered using a computer to be maintained in individual computer disk data files. A code will be used to identify the volunteer, and a master list with the volunteer's name will be developed. The data will be available only to the investigators and selected laboratory personnel. When not being analyzed, data and treatment codes will be maintained in locked file cabinets in NHRC Building 28. This information will be used for research purposes only, and data will be reported anonymously so that volunteers cannot be identified.

2. Research Protocol, Consent Forms, and Related Documents for Protection of Human Research Volunteers

The principal investigator will keep the research protocols and consent forms in a locked file in Bldg. 28, NHRC. Computer data files will be stored in compliance with NAVMEDRSCHDEVCOMINST 5870.4.

3. Individual Medical Records

Each volunteer will be asked to bring his or her medical records to the testing session for the validation study. While at the laboratory, the records will be secured in a locked file cabinet. These records will be returned to the volunteer at the conclusion of the test session. Medical records will not be required for the field study.

X. APPENDICES

Appendix A. SAMPLE OF CONSENT DOCUMENTS AND PRIVACY ACT STATEMENT
USED

Body Composition of U.S. Marine Corps and Other Military Personnel:
Validation of USMC Body Fat Prediction Equations

VOLUNTARY CONSENT TO PARTICIPATE

1. I am being asked to volunteer to participate in a research study titled, "Body Composition of U.S. Marine Corps and Other Military Personnel: Validation of USMC Body Fat Prediction Equations." The purposes of this study are to determine the accuracy of the USMC's circumference-based equations for determining percent body fat, to determine affects of ethnicity on body composition prediction for women, and to determine the validity of bioelectrical impedance measurement to estimate total body water. To meet these aims, my body composition will be determined from measurement of my bone density, total body water, and body density. This is currently the most accurate method of assessing body composition in humans. I am being asked to participate between December 1997 and July 1998. I will be asked to visit the laboratory once, for a total of 4.5 hours. Approximately 500 volunteers will participate in this study. During my participation in this study, I will be involved in the following procedures or tests:

I will bring my medical records to the laboratory at Building 74, Fleet Combat Training Center, Pacific. I will read and sign an informed consent form, and I will complete a medical history questionnaire. My medical record and questionnaire will be reviewed and an entry will be made into my record showing that I am participating in this study. I will also complete a form asking me about my history of exercise and/or sports participation.

I will participate in the tests described as follows. During the testing I will wear a swimsuit.

(1) Body measurements: I will have my height and weight measured. Body circumferences (18 sites) will be measured with two different measuring tapes, skinfold thickness (10 sites) with a skinfold caliper, and bone breadths (10 sites) with a sliding caliper. These measurements are taken to assess body configuration and body fat percentage using the present Navy equations and the new equations that have been developed at the Naval Health Research Center.

(2) Bioimpedance analysis: Bioimpedance analysis is the measurement of the body's resistance to a small, undetectable electrical current. I will lie on my back on a padded table. Small areas on my wrist, hand, ankle, and foot will be cleansed with alcohol, and four disposable, adhesive electrodes will be applied. A painless, imperceptible current will be passed through my body for a few seconds. My body's resistance to the current will be measured to assess my total body water. Body resistance is directly related to body water

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content because the electrolytes in body water conduct electrical current.

(3) Total body water (deuterium oxide): I will be asked to empty my bladder of urine. Afterward, I will drink a small amount of a safe, naturally occurring form of water called deuterium oxide. At three times I will have my respiratory water collected: before ingesting the D2O, 3 hours post ingestion, and 4 hours post ingestion. To do this, I will inhale through my nose and exhale through my mouth into a 1.5 meter length of tubing. As my breath passes through the tubing, concentric loops of the tubing will be submerged in an methanol-dry ice bath at 60°C. Submerging the tubing will cause my respiratory vapors to condense on the inside of the tubing. I will continue to breath, inhaling nasally and exhaling orally, through the tubing for 6 to 15 min to allow a sufficiently large sample of respiratory water to be collected. After the collection period, the condensed respiratory vapors will be thawed and poured into a microtube for storage, and later analysis. I may also be asked to provide a urine sample two and three hours after drinking the D2O. The amount of deuterium oxide the researchers detect in my respiratory water and/or urine will allow the researchers to determine the total amount of water in my body. Results from this test will be used to check the accuracy of body water determined by the bioimpedance method.

(4) DEXA scan: I will lie on my back on a padded table for 12 minutes while a low-energy x-ray beam scans my entire body to determine bone mineral content, bone density, fat mass, and fat-free mass. The radiation dose for this scan is very low, 1 mrem, which is equivalent to one 250th of normal annual background radiation, one 9th of the radiation received in a transatlantic flight, or one 30th of a chest x-ray.

(5) Residual lung volume: This test will be done to determine the volume of air remaining in my lungs after a maximal exhalation. Results will be used in body density calculations. I will wear a nose clip and breathe through a mouthpiece connected to a device that contains room air and a small amount of helium (5% to 10%). After exhaling maximally, I will breathe normally on the system for 2 to 3 minutes; during that time, ample oxygen will be supplied to the system. After the 2 to 3 minutes, I will exhale maximally again to finish the test.

(6) Underwater weighing: My weight underwater will be measured to determine my body density and percent body fat. I will sit, with my head above the water, on a chair suspended from a weighing device, in a 4-foot-deep, glass-fronted tank of heated water (95°F). I will be asked to exhale all of my air, bend forward at the waist until my body is completely submerged, and remain motionless for several seconds until stable weights have been recorded. I may raise my head above

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the water anytime I wish by simply sitting up straight in the chair or standing on the bottom of the tank. I will be asked to repeat the procedure for a total of 6 to 10 times, with rest allowed between each effort.

All of these testing procedures are considered routine.

2. The investigators believe the risks and discomforts to me associated with the proposed study are as follows: No risk is associated with body measurements, bioimpedance analysis, or deuterium oxide ingestion.

Low risk is posed by the radiation dose of the 12-minute, whole body DEXA scan (1.0 mrem), which is equivalent to approximately one 250th of normal annual background radiation, one 9th of the radiation received in a transatlantic flight, or one 30th of the radiation received in a chest x-ray. The radiation dose of the DEXA whole body scan is 1 mrem, which one 5000th of the radiation dose that the National Council on Radiation Protection and Measurements considers to be a negligible risk to an embryo or fetus. Although the risk of fetal malformation due to a DEXA scan is low, any unnecessary radiation should be avoided during pregnancy. Therefore, if I am pregnant or think I might be pregnant, I should not undergo the DEXA scan.

Residual lung volume measurement poses a slight risk of discomfort associated with breathing through a mouthpiece and wearing a nose clip. If I experience any distress while breathing into the residual volume machine, I may simply remove my mouthpiece to discontinue the test. During underwater weighing there is a theoretical risk of drowning, although none has ever been reported during more than 30 years of widespread use of this technique. There is a very small risk of inhaling water during the underwater testing. If this occurs, I can sit up to bring my head above water. All testing staff are trained in cardiopulmonary resuscitation (CPR). Thus, if a person stops breathing and/or his or her heart stops beating, the staff is trained to provide artificial breaths and heart compressions to sustain life. The staff is also trained in the procedure for quickly removing an unconscious person from the underwater weighing tank.

3. The only direct benefit that I may expect from my participation in this research is the knowledge of my body fat percentage and bone density. This research is expected to benefit the United States Marine Corps, as well as the other Services by determining if the current circumference method of determining body fat percentage is accurate. The Services will also benefit from knowing whether or not bioelectric impedance analysis can be used to accurately estimate total body water, and thus prove practical for use in body composition estimation, and whether or not there is a need to take ethnicity into account when estimating body composition from anthropometry.

4. My confidentiality during the study will be ensured by keeping all papers collected during my participation in a secure filing cabinet at the Naval Health Research Center, San Diego, CA. My files will be accessible only to the investigators of this study. The confidentiality of the information related to my participation in this research will be protected through the maintenance of electronic data sets (computer files) that do not contain any information that can identify me

Your Initials _____

personally. Computer data files will be stored in compliance with NAVMEDRSCHDEVCOMINST 5870.4. In addition, in all publications and presentations resulting from this research study, information about me or my participation in this project will be kept in the strictest confidence. However, I realize that authorized personnel from the Navy Medical Department, the Food and Drug Administration (FDA), or other official agencies may have access to my research file to verify that my rights have been adequately protected.

5. If I have questions about this study I should contact the following individuals: for questions about research (science) aspects contact LCDR Kathleen Kujawa at (619) 524-1864 or Ms. Katherine Canine at (619) 524-4517; for questions about medical aspects, injury, or any health or safety questions I have about my or any other volunteer's participation, contact the medical monitor, CAPT Greg Gray at (619) 553-9967; and for questions about the ethical aspects of this study, my rights as a volunteer, or any problem related to protection of research volunteers, contact Dr. Ross Vickers, chair of the Committee for Protection of Human Subjects, at (619) 524-4525.

6. My participation in this study is completely voluntary. If I do not want to participate, there will be no penalty, and I will not lose any benefit to which I am otherwise entitled. I may discontinue my participation in this study at any time I choose. If I do stop, there will be no penalty, and I will not lose any benefit to which I am otherwise entitled.

7. To my knowledge I am not pregnant at this time.

8. I have received a statement informing me about the provisions of the Privacy Act.

9. I have been informed that Lcdr Kathleen Kujawa, MSC, USN, is responsible for storage of my consent form and the research records related to my participation in this study. These records will be stored in a locked file cabinet at the Human Performance Department, Naval Health Research Center.

Your Initials _____

10. I have been given an opportunity to ask questions about this study and its related procedures and risks, as well as any of the other information contained in this consent form. All of my questions have been answered to my satisfaction. By my signature below, I give my voluntary informed consent to participate in the research as it has been explained to me, and I acknowledge receipt of two copies of this form one for my medical records and one for my own personal records.

Volunteer:

Signature	Printed Name	Date
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Witness:

Signature	Printed Name	Date
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Investigator:

Signature	Printed Name	Date
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Body Composition of U.S. Marine Corps Personnel:
Field Survey of Body Composition of USMC Personnel

VOLUNTARY CONSENT TO PARTICIPATE

1. I am being asked to volunteer to participate in a research study titled, "Body Composition of U.S. Marine Corps Personnel: Field Survey of Body Composition of USMC Personnel." The purpose of this study is to conduct a survey of body composition (percent body fat) of active-duty Marine Corps personnel. To determine the body composition of USMC personnel, my percent body fat will be determined by the USMC circumference method and by the skinfold method. I am being asked to participate sometime between January 1998 and July 1998. I will be measured once using each method, and all measurements will take a total of approximately 20 minutes. Approximately 1,700 volunteers will participate in this study. During my participation in this study, I will be involved in the following procedures or tests:

I will participate in the body measurement tests. I will have my height and weight measured. Body circumferences (5 sites) will be measured with a measuring tape, and skinfold thickness (10 sites) with a skinfold caliper. These measurements are taken to calculate body fat percentage using the current USMC equations and equations that use skinfold measurements.

These testing procedures are considered routine.

2. The investigators believe no risk or discomfort to me is associated with the proposed study.

3. There is no direct benefit to me from this test. This research is expected to benefit USMC personnel, in general, by determining the current body composition of USMC personnel by age and ethnicity.

4. My confidentiality during the study will be ensured by keeping all papers collected during my participation in a secure filing cabinet at the Naval Health Research Center, San Diego, CA. My files will be accessible only to the investigators of this study. The confidentiality of the information related to my participation in this research will be protected through the maintenance of electronic data sets (computer files) that do not contain any information that can identify me personally. Computer data files will be stored in compliance with NAVMEDRSCHDEVCOMINST 5870.4. In addition, in all publications and presentations resulting from this research study, information about me or my participation in this project will be kept in the strictest confidence. However, I realize that authorized personnel from the Navy Medical Department, the Food and Drug Administration (FDA), or other official agencies may have access to my research file to verify that my rights have been adequately protected.

5. If I have questions about this study I should contact the following individuals: for questions about research (science)

aspects contact LCDR Kathleen Kujawa at (619) 524-1864 or Ms. Katherine Canine at (619) 524-4517; for questions about medical aspects, injury, or any health or safety questions I have about my or any other volunteer's participation, contact the medical monitor, CAPT Greg Gray at (619) 553-9967; and for questions about the ethical aspects of this study, my rights as a volunteer, or any problem related to protection of research volunteers, contact Dr. Ross Vickers, chair of the Committee for Protection of Human Subjects, at (619) 524-4525.

6. My participation in this study is completely voluntary. If I do not want to participate, there will be no penalty, and I will not lose any benefit to which I am otherwise entitled. I may discontinue my participation in this study at any time I choose. If I do stop, there will be no penalty, and I will not lose any benefit to which I am otherwise entitled.

7. To my knowledge I am not pregnant at this time.

8. I have received a statement informing me about the provisions of the Privacy Act.

9. I have been informed that LCDR Kathleen Kujawa, MSC, USN, is responsible for storage of my consent form and the research records related to my participation in this study. These records will be stored in a locked file cabinet at the Human Performance Department, Naval Health Research Center.

10. I have been given an opportunity to ask questions about this study and its related procedures and risks, as well as any of the other information contained in this consent form. All of my questions have been answered to my satisfaction. By my signature below, I give my voluntary informed consent to participate in the research as it has been explained to me, and I acknowledge receipt of a copy of this form for my own personal records.

Volunteer:

Signature	Printed Name	Date
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Witness:

Signature	Printed Name	Date
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Investigator:

Signature	Printed Name	Date
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PRIVACY ACT STATEMENT

1. Authority. 5 U.S.C. 301

2. Purpose. Medical research information will be collected in an experimental research project titled, "Body Composition of U.S. Marine Corps and Other Military Personnel," to enhance basic medical knowledge, or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or performance impairment.

3. Routine Uses. Medical research information will be used for analysis and reports by the Departments of the Navy and Defense, and other U.S. Government agencies. Use of the information may be granted to non-Government agencies or individuals by the Navy Surgeon General following the provisions of the Freedom of Information Act or contracts and agreements. I voluntarily agree to its disclosure to agencies or individuals identified above, and I have been informed that failure to agree to this disclosure may make the research less useful. The "Blanket Routine Uses" that appear at the beginning of the Department of the Navy's compilation of medical data bases also apply to this system.

4. Voluntary Disclosure. Provision of information is voluntary. Failure to provide the requested information may result in failure to be accepted as a research volunteer in an experiment, or removal from the program.

See Attached: Consent statement for this experiment, signed by the volunteer.

Appendix B. INVESTIGATOR ASSURANCE AGREEMENT(s)

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled, "Body Composition of U.S. Marine Corps and Other Military Personnel," have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), Secretary of the Navy Instruction (SECNAVINST) 3900.39B (Protection of Human Subjects), Naval Medical Command Instruction (NAVMEDCOMINST) 6710.4 "Use of Investigational Agents in Human Beings" - if applicable), and Naval Medical Research and Development Command Instruction (NMRDCINST) 3900.2 (Protection of Human Research Volunteers from Research Risks), SECNAVINST 5370.2H (Standards of Conduct) (and local instructions, as applicable). I will abide by all applicable laws and regulations, and I agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chair, Committee for the Protection of Human Subjects. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chair, Committee for the Protection of Human Subjects.

Signatures and dates:

(DD/MM/YY)

Keith Prusaczyk, Ph.D.
Head, Human Performance Department

____/____/____

LCDR Kathleen I. Kujawa, MSC, USN
Principal Investigator

____/____/____

M. Katherine Canine, M.A.
Co-Investigator

____/____/____

James A. Hodgdon, Ph.D.
Co-Investigator

____/____/____

Appendix C. REVIEW FOR PROTECTION OF HUMAN RESEARCH VOLUNTEERS FROM RESEARCH RISKS

1. Recommendation(s) of the Committee for the Protection of Human Subjects (CPHS)
2. Minutes of the Meeting of the CPHS
3. Recommendation of the Convening Authority
4. Action of the Approving Authority
5. Other Documentation (as required)
 - a. Unlabeled use of approved drugs or licensed biologics
Provide documentation from the Food and Drug Administration (FDA) authorizing exemption from the requirement for Investigational New Drug Application (IND)
 - b. Experimental drugs, biologics or devices
 1. Documentation of an approved IND or Investigational Device Exemption (IDE) from the FDA
 2. Approval of the Naval Investigational Drug Review Board (NIDRB)
 - c. Documentation of review and action taken by all collaborating institution(s)
 1. Acceptable results of review are: approval, exemption from review, joint review, or other formal review agreement
 2. Certification by the principal investigator that protocol submitted for review is the same final copy approved or under simultaneous review by collaborating institution(s)
 - d. Host Government Approval if Research Is Performed in a Foreign Country
 - e. Legal Issues
 1. Sufficiency of third party permission
 - a. Citation of statutory authority
 - b. CPHS determination regarding requirement for assent
 2. Citation of statutory authority for compensation of volunteers

3. Other

- f. OPNAV Form 5214-10 (if required for questionnaire survey—include CNO approval document)
- g. Request for waiver of requirement(s) for protection of human research volunteers
- h. Documentation of exemption from compliance with regulations for the protection of human research volunteers (State authority and criteria for exemption)

I. Other

Appendix D. POSTAPPROVAL DOCUMENTATION

1. Change of investigator(s), medical monitor, or collaborating institution(s) (addition or deletion)
2. Significant modification(s) to the protocol
3. CPHS continuing review (annually)
 - a. Reviewed by NAVMEDRSCHDEVCOM activity
 - b. Review by collaborating institution(s)
 - c. Modification of CPHS recommendations
4. Documentation of all official action since initial submission and review

Appendix E. SPECIAL REPORTS

1. Unanticipated complications or problems
2. Reports of noncompliance with requirements for protection of human research volunteers
3. Adverse CPHS action
 - a. Recommendation for suspension
 - b. Recommendation for termination
4. Resulting action by convening and approving authorities

Appendix F. REFERENCES

- Friedl, K. E., J. P. DeLuca , L. J. Marchitelli, and J. A. Vogel. 1992. Reliability of body-fat estimations from a four-compartment model by using density, body water, and bone mineral measurements. American Journal of Clinical Nutrition 55:764-70.
- MCO 6100.10B Ch 2. 1995. Marine Corps Order 6100.10B Ch 2, Weight Control and Military Appearance.
- Nunnally, J. C., and I. H. Bernstein. 1994. Psychometric Theory, 3rd ed. New York: McGraw-Hill.
- Patel, R. V., J. R. Matthie, P. O. Withers, E. L. Peterson, and B. J. Zarowitz. 1994. Estimation of total body water and extracellular water using single- and multiple-frequency bioimpedance. Annals of Pharmacotherapy 28:565-9.
- Ruppel, G. 1975. Manual of Pulmonary Function Testing. The C.V. Mosby Co., St. Louis, MO.
- Van Loan, M. D., P. Withers, J. Matthie, and P. L. Mayclin. 1993. Use of bioimpedance spectroscopy to determine extracellular fluid, intracellular fluid, total body water, and fat-free mass. In: K. J. Ellis and J. D. Eastman (Eds.), Human Body Composition pp. 67-70. New York: Plenum Press.

Appendix G. CURRENT PHYSICAL ACTIVITY QUESTIONNAIRE